DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 12, 2015

TELEEMG, LLC USA
% Mr. Barry Ashar
President
Enter consultant name here, or erase this if there is none
88 Stiles Road
Salem, NH 03079

Re: K141524
Trade/Device Name: NEURO-AUDIO
Regulation Number: 21 CFR 874.1050
Regulation Name: Audiometer
Regulatory Class: Class II
Product Code: EWO, GWJ
Dated: February 6, 2015
Received: February 10, 2015

Dear Mr. Ashar,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141524

Device Name
Neuro-Audio

Indications for Use *(Describe)*
The Neuro-Audio system is indicated for use in the recording and analysis of human physiological data used for the diagnosis of auditory and hearing-related functions. It is intended as an aid to healthcare professionals trained and skilled in audiology. The system assists in the evaluation, documentation and diagnosis of ear disorders in humans using evoked potentials (EP), electrocochleography (ECochG), auditory brainstem response (ABR), auditory steady-state response (ASSR), otoacoustic emission (OAE) and pure tone audiometry (PTA).

The device is intended for use in the patient care institutions, diagnostics centers, neurosurgical hospitals and experimental laboratories.

The patient group includes all ages and genders.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
Neuro-Audio

1. SUBMITTER/510(K) HOLDER

TeleEMG, LLC
65 Arlington Road
Woburn, MA 01801, USA
Contact Person:
Barry V. Ashar,
Makromed, Inc.
Telephone: (603) 890-3311
Date Prepared: August 19, 2014

2. DEVICE NAME

Proprietary Name: Neuro-Audio
Common/Usual Name: Audiometer
Classification Name: Audiometer; Stimulator, Auditory, Evoked Response
Regulation Number: 21 CFR §874.1050; 21 CFR §882.1900
Device Class: Class II
Product Code: EWO; GWJ

3. PREDICATE DEVICES

- Interacoustics EP25, Eclipse System, K052562
- Interacoustics TEOAE25, Eclipse System, K030016
- Interacoustics DPOAE2O, Eclipse System, K060539
- Interacoustics ASSR, Eclipse System, K070696
- Interacoustics Affinity (AC440), K043219
- GSI Audera, K011135

4. DEVICE DESCRIPTION

The Neuro-Audio system provides for audiology biopotentials recording and input to personal computer (PC) by 1-2 channels, and measurement, calculation and analysis of its parameters. It can be used in patient care institutions, diagnostics centers, neurosurgical hospitals and experimental laboratories of the research institutions for auditory tract study and brain functional state study.

General functionalities provided by the system are:

- biopotentials acquisition by 1-2 channels in any unshielded room
- auditory stimulation
- electrocochleography (ECochG) acquisition
- auditory brainstem response (ABR) acquisition (air and bone conduction)
- middle- and long-latency auditory evoked potentials (AEP: MLR, LLR) acquisition
- cognitive evoked potentials (MMN, P300) acquisition
- auditory steady-state response (ASSR) acquisition
- otoacoustic emission study using transient evoked otoacoustic emission (TEOAE) and distortion product otoacoustic emission (DPOAE)
- spontaneous otoacoustic emission study (SOAE)

- pure tone audiometry (PTA; air and bone conduction)
- exam report generation
- review, store, and print of the recorded traces, results of their analysis and exam reports.

In addition, the Neuro-Audio system provides the healthcare professional with:

- A means of adjusting or activating all of the unit's settings and controls.
- Multiple ways in which a user can carry a task, such as from a menu, using the mouse or the keyboard or by double-clicking on an icon.
- Configurable function keys and fields that enable the user to customize the interface to meet their requirements.
- Single-stroke keyboard function keys for key tasks carried out during a patient examination.

5. INTENDED USE

The Neuro-Audio system is indicated for use in the recording and analysis of human physiological data used for the diagnosis of auditory and hearing-related functions. It is intended as an aid to healthcare professionals trained and skilled in audiology. The system assists in the evaluation, documentation and diagnosis of ear disorders in humans using evoked potentials (EP), electrocochleography (ECochG), auditory brainstem response (ABR), auditory steady-state response (ASSR), otoacoustic emission (OAE) and pure tone audiometry (PTA).

The device is intended for use in the patient care institutions, diagnostics centers, neurosurgical hospitals and experimental laboratories.

The patient group includes all ages and genders.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

All the necessary electromagnetic compatibility and electrical safety tests were performed. The results demonstrate that the Neuro-Audio is in compliance with both the standards IEC 60601-1-2 and IEC 60601-1; therefore it is as safe as the predicate devices.

Each system consists of an electronic unit connected to a personal computer to monitor, record, and display the signals. Some accessories are not included in the Neuro-Audio (for example, in the case of "Footswitch for hands-free operation"). However, this is entirely optional (most predicate devices don't have it either) and will not harm the intended use. Each clinically relevant feature and supported medical diagnostic test of the Neuro-Audio is also implemented in at least one (or more) predicate device(s) The differences between the Neuro-Audio and the predicate devices are limited to the design, materials and the individual sets of medical hearing diagnostic tests they support (e.g. one predicate device may support one of the Neuro-Audio's diagnostic tests, some other predicate devices may support another test). There is no single predicate device possess all the functions the Neuro-Audio supports, that's the reason several predicate devices are included to demonstrate the substantial equivalency. The software may differ in visual appearance, layout of control elements, the way of displaying test results. But the underlying principles and all the provided test results are substantially the same among the Neuro-Audio and the predicate devices (e.g., if the software should show the averaged response trace for ABR test, the Neuro-Audio may show it in different color than its predicate devices, but it still shows the averaged response trace; if there is a PASS/REFER result for TEOAE

screening test, different software may show different additional information, but the Neuro-Audio still covers the most important part –PASS/REFER result; etc.). Therefore, TeleEMG concludes that design differences (both hardware and software) are minor and do not affect the safety and effectiveness of the proposed device.

Based on the comparison and the discussion above, TeleEMG claims that the Neuro-Audio and all predicate systems are substantially equivalent.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Performance Testing
Performance evaluation of the features described in the Neuro-Audio user manual has been successfully completed utilizing hardware and software tests and validations. Hardware qualification is performed using the following industry standards:

- IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility requirements and tests
- IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for safety and essential performance - Collateral standard: Usability
- IEC 60645-1:2012 Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone audiometry
- IEC 60645-6:2009 Electroacoustics - Audiometric equipment - Part 6: Instruments for the measurement of otoacoustic emissions
- IEC 60645-7:2009 Electroacoustics - Audiometric equipment - Part 7: Instruments for the measurement of auditory brainstem responses

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE
No clinical testing was conducted to support this submission.

9. SUMMARY OF OTHER INFORMATION
No other information is available.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS
Based on the information and supporting documentation provided in the premarket notification, the Neuro-Audio is substantially equivalent to the cited predicate devices. Testing demonstrates that the Neuro-Audio fulfills prospectively defined design and performance specifications.